Complete Summary

GUIDELINE TITLE

National guideline for the management of bacterial vaginosis (2006).

BIBLIOGRAPHIC SOURCE(S)

Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH). National guideline for the management of bacterial vaginosis. London (UK): British Association for Sexual Health and HIV (BASHH); 2006. 14 p. [40 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline for the management of bacterial vaginosis. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [27 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bacterial vaginosis

GUIDELINE CATEGORY

Diagnosis
Evaluation

Management
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To assist practitioners in managing women diagnosed with bacterial vaginosis (BV)

TARGET POPULATION

Women in the United Kingdom with bacterial vaginosis (BV)

Note: The guideline is aimed primarily at people aged 16 years or older (see specific guidelines for those under 16).

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Evaluation of vaginal discharge using the Amsel criteria
2. Microscopic assessment of a gram stained vaginal smear, with the Hay/Ison or Nugent criteria

Treatment/Management

1. General advice to patients
2. Treatment
    - Metronidazole, oral or intravaginal cream or gel
    - Clindamycin, oral or intravaginal cream
    - Tinidazole, oral
3. Prevention of relapse (the following are considered, but no recommendations are made)
    - Metronidazole, intravaginal gel or oral (combined with fluconazole)
    - Acigel
    - Yogurt (considered but not recommended)
    - Antibiotics with probiotic therapy and hydrogen peroxide
4. Sexual partner management
5. Follow-up

MAJOR OUTCOMES CONSIDERED

Cure rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An extensive literature reviewed was carried out using Medline for the years 1970 to 2005 using the keyword "bacterial vaginosis." The Cochrane library was searched using "bacterial vaginosis." Previous guidelines were sought, and the 1998 and 2002 U.S. guidelines reviewed.

Where available, systematic reviews were used. Additionally, randomised clinical trials (RCTs) and review articles were referenced. Only English language papers were used. The previous 2001 guidelines were used as a basis. Where feedback from clinicians indicated areas of controversy these were reviewed, and areas in which new RCTs had been published were reviewed. Expert opinion was sought for difficult areas such as the management of bacterial vaginosis in pregnancy.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials
Ib: Evidence obtained from at least one randomised controlled trial
IIa: Evidence obtained from at least one well designed controlled study without randomisation
IIb: Evidence obtained from at least one other type of well designed quasi-experimental study
III: Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies
IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This guideline was produced by medical specialists from relevant disciplines. Successive drafts have been reviewed by the clinical effectiveness group of the British Association for Sexual Health and HIV (BASHH). Expert opinion was sought for difficult areas such as the management of bacterial vaginosis in pregnancy.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

A (Evidence Levels Ia, Ib)

- Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

- Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Successive drafts of the guideline have been reviewed by the clinical effectiveness group of the British Association for Sexual Health and HIV (BASHH).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis

Two approaches are available:

- Amsel criteria. At least three of the four criteria are present for the diagnosis to be confirmed.
    1. Thin, white, homogeneous discharge
    2. Clue cells on microscopy of wet mount
    3. pH of vaginal fluid >4.5
    4. Release of a fishy odour on adding alkali (10% potassium hydroxide [KOH])
- A Gram stained vaginal smear, evaluated with the Hay/Ison criteria or the Nugent criteria.

  The Hay/Ison criteria are defined as follows:

  Grade 1 (Normal): Lactobacillus morphotypes predominate
  Grade 2 (Intermediate): Mixed flora with some Lactobacilli present, but Gardnerella or Mobiluncus morphotypes also present
  Grade 3 (bacterial vaginosis [BV]): Predominantly Gardnerella and/or Mobiluncus morphotypes. Few or absent Lactobacilli

  The Nugent score is derived from estimating the relative proportions of bacterial morphotypes to give a score between 0 and 10. A score of <4 is normal, 4 to 6 is intermediate, and >6 is BV.

The Bacterial Special Interest group of British Association for Sexual Health and HIV (BASHH) recommend using the Hay/Ison criteria in Genitourinary medicine clinics (**C**).

Management

General Advice

Patients should be advised to avoid vaginal douching, use of shower gel, and use of antiseptic agents or shampoo in the bath (**C**).

Treatment

Treatment is indicated for:

- Symptomatic women (**A**)
- Women undergoing some surgical procedures (**A**)

Women who do not volunteer symptoms may elect to take treatment if offered. They may report a beneficial change in their discharge following treatment.

Recommended Regimens

- Metronidazole 400-500 mg twice daily for 5-7 days (**A**)

  or

- Metronidazole 2 g single dose (**A**)

Alternative Regimens

- Intravaginal metronidazole gel (0.75%) once daily for 5 days (**A**)

  or

- Intravaginal clindamycin cream (2%) once daily for 7 days (**A**)

  or

- Clindamycin 300 mg twice daily for 7 days (**A**)

  or

- Tinidazole 2 g single dose (**A**)

Caution

- With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present.
- Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported with both oral clindamycin and clindamycin cream.

Allergy

Allergy to metronidazole is uncommon. Use 2% clindamycin cream for metronidazole allergic women.

Pregnancy and Breast Feeding

The results of clinical trials investigating the value of screening for and treating bacterial vaginosis in pregnancy have been conflicting. It is therefore difficult to

make firm recommendations. A detailed discussion of trials in pregnancy is in the appendix of the original guideline document. In conclusion:

- Symptomatic pregnant women should be treated in the usual way (**B**).
- There is insufficient evidence to recommend routine treatment of asymptomatic pregnant women who attend a genitourinary (G-U) clinic and are found to have bacterial vaginosis.
- Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding. Small amounts of clindamycin enter breast milk. It is prudent therefore to use an intravaginal treatment for lactating women (**C**).

Termination of Pregnancy (TOP)

Three studies have investigated whether antibiotics can reduce the rate of infectious morbidity in women with BV, following termination of pregnancy. A Scandinavian study of 231 women demonstrated a reduction in post-TOP infection by treating BV with oral metronidazole before termination (**Ib**). Another demonstrated a reduction in infective complications following the use of clindamycin cream (**Ib**). A United Kingdom study of 273 women again found a reduction in post-operative upper genital tract infection from 16% to 8.5%, but did not quite reach statistical significance. There are no data on the effectiveness of treatment administered at the time of TOP.

- These studies support screening for and treating BV with either metronidazole or clindamycin cream, to reduce the incidence of subsequent endometritis and pelvic inflammatory disease (PID) (**Ia**).

Sexual Partners

- No reduction in relapse rate was reported from two studies in which male partners of women with bacterial vaginosis were treated with metronidazole, one study of tinidazole, and one of clindamycin (**Ib**). Routine screening and treatment of male partners are therefore not indicated.
- Two studies reported a high incidence of bacterial vaginosis in female partners of lesbian women with bacterial vaginosis (**II**). No study has investigated the value of treating partners of lesbian women simultaneously.

Follow Up

A test of cure is not required if symptoms resolve.

Recurrent Bacterial Vaginosis

There are few published studies evaluating the optimal approach to women with frequent recurrences of BV. Possible approaches are as follows:

- Suppressive therapy. Metronidazole gel 0.75%. twice weekly for 4 to 6 months to decrease symptoms, after an initial treatment daily for 10 days, is being evaluated.

- Metronidazole orally 400 mg twice a day (bd) for 3 days at the start and end of menstruation, combined with fluconazole 150 mg as a single dose if there is a history of candidiasis also (**III**).
- A recent observational study reported that acigel used at the time of menstruation and following unprotected sexual intercourse was associated with a reduction in relapse rate following a course of metronidazole (**III**).
- Small studies of live yoghurt *or Lactobacillus acidophilus* have not demonstrated benefit (**IIa**).
- Other treatments being studied at present include the use of combinations of antibiotics with probiotic therapy and hydrogen peroxide.

Definitions:

Levels of Evidence

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Grades of Recommendation

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C (Evidence Level IV)

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- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Accurate diagnosis and appropriate treatment of bacterial vaginosis
- The recommended and alternative treatments have been shown to achieve cure rates of 70% to 80% after 4 weeks in controlled trials using placebo or comparison with oral metronidazole.

POTENTIAL HARMS

- With metronidazole treatment alcohol should be avoided because of the possibility of a disulfiram-like action. There are no data on the risks from consuming alcohol with intravaginal metronidazole gel, but it is not recommended at present.
- Clindamycin cream can weaken condoms, which should not be used during such treatment. Pseudomembranous colitis has been reported with both oral clindamycin and clindamycin cream.
- Metronidazole enters breast milk and may affect its taste. The manufacturers recommend avoiding high doses if breast feeding. Small amounts of clindamycin enter breast milk.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources.
- All possible care has been undertaken to ensure the publication of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2006 Jan)

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The author has declared potential conflicts of interest.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the British Association for Sexual Health and HIV Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug;75(Suppl 1):S2-3.
- Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002;78:81-2

Print copies: For further information, please contact the journal publisher, BMJ Publishing Group.

Additionally, auditable outcome measures are available in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002. This NGC summary was updated by ECRI Institute on December 12, 2007. The updated information was verified by the guideline developer on February 7, 2008.

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